Remarks

Claims 1 to 95 were pending and before the Examiner. By this Amendment, applicants have amended claims 38 and 81. Furthermore, applicants have amended the disclosure to insert terms to refer to each of the nebulizer types specified in the disclosure: the nebulizers set forth in PCT Publication No. WO 91/14468 are designated "the Weston Nebulizer"; the nebulizers set forth in PCT Application No. WO 97/12687 are designated "the Jaeger Nebulizer A"; and the nebulizer portrayed in Fig. 6 of PCT Application No. WO 97/12687 is designated "the Jaeger Nebulizer B". Claims 38 and 81 therefore refer to the nebulizers set forth in PCT Publication No. WO 91/14468 and the nebulizer portrayed in Fig. 6 of PCT Application No. WO 97/12687, respectively. Applicants maintain that no new matter has been added thereby and therefore request that these amendment be entered. Claims 1 to 95 are now pending and before the Examiner in this application.

The Examiner rejected claims 38, 42, 44, 46, 48, 51, 81, 85, 87, 89, 91, and 94 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In response, applicants have amended the claims and disclosure and traverse the Examiner's rejection insofar as it requires incorporation of the voluminous disclosure of these applications, as applicants do not believe they are essential material. As the Examiner may know, however, WO 97/20590 is the equivalent of U.S. Patent No. 6,453,795; WO 97/12687 is the equivalent of U.S. Patent No. 5,964,416; and WO 91/14468 is the equivalent of U.S. Patent No. 5,497,944. Accordingly, applicants would be willing to insert appropriate statements in the disclosure, for example, "U.S. Patent No. 5,497,944 (equivalent to WO 91/14468) is hereby incorporated by reference" in required places where PCT documents are incorporated by reference to satisfy the Examiner.

The Examiner rejected claims 1 to 37, 50, 53 to 80 and 93 under 35 U.S.C. § 102(b), as allegedly anticipated by Freund *et al.* (DE 19653969; U.S. Patent Application Publication No. US 2001/0008632 being used as a translation thereof).

In response, applicants respectfully traverse the Examiner's rejection. Freund *et al.* relates generally to aqueous medicament preparations. Although Freund *et al.* may mention certain

elements of applicants' claimed invention, Freund *et al.* does not provide any disclosure or embodiment of the combination of applicants' claimed invention. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co.*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); *see also* M.P.E.P. § 2131. Accordingly, there is no anticipation of the claimed invention by Freund *et al.* and applicants respectfully request that the Examiner reconsider and withdraw this rejection.

The Examiner also rejected claims 38 to 49, 51, 52, 81 to 92, 93, and 95 under 35 U.S.C. § 103(a), as allegedly unpatentable over Freund *et al.* and further in view of Weston *et al.* (WO 91/14468).

In response, applicants respectfully traverse the Examiner's rejection under 35 U.S.C. § 103(a) and maintain that the Examiner has failed to establish a *prima facie* case of obviousness against the instant invention. A *prima facie* case of obviousness requires the satisfaction of three criteria: (i) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings; (ii) there must be a reasonable expectation of success; and (iii) the references when combined must teach or suggest all of the claim limitations. M.P.E.P. § 2143.

Neither Freund *et al.* nor Weston *et al.*, alone or in combination, renders the special formulation of applicants claimed invention obvious, however, since neither reference, alone or in combination discloses, suggests, or even hints to one of skill in the art, much less with the required reasonable expectation of success, of the claimed combination of applicants' invention. As pointed out above, with respect to the anticipation rejection, Freund *et al.* does not provide any disclosure or embodiment of the combination of applicants' claimed invention. Since the Examiner is relying solely on Freund *et al.* to teach the formulation to be used in the nebulizer of Weston *et al.*, applicant maintains that Freund *et al.* is deficient in teaching the formulation used in applicants' claimed invention. The Examiner has the burden of showing a *prima facie* case of obviousness. *In re Bell*, 26 U.S.P.Q.2d 1529, 1530 (Fed. Cir. 1993); *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). The fact that Freund *et al.* nor Weston *et al.* contain elements of applicants' claimed invention alone does not render

the claimed invention obvious. Rejecting claims solely by finding prior art corollaries for the claimed elements would permit an Examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention, which is an illogical and inappropriate process by which to determine patentability. *Sensonics, Inc. v. Aerosonic Corp.*, 38 U.S.P.Q.2d 1551, 1554 (Fed. Cir. 1996); *In re Rouffet*, 47 U.S.P.Q.2d 1453 (Fed. Cir. 1998). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion or incentive to do so. *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Virtually all inventions are combinations of old elements. *Environmental Designs, Ltd. v. Union Oil Co.*, 218 U.S.P.Q. 865, 870 (Fed. Cir. 1983). Thus, the mere mention of elements of applicants' claimed invention in these references does not alone render obvious their particular combination. As applicants maintain that the Examiner has failed to establish a *prima facie* case of obviousness against the instant invention, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

The Examiner also rejected claims 1 to 37, 50, 53 to 80 and 93 under 35 U.S.C. § 102(b), as allegedly anticipated by Bozung *et al.* (DE 19921693; U.S. Patent No. 6,433,027 being used as a translation thereof).

In response, applicants respectfully traverse this rejection and maintain that Bozung *et al.* is not a proper reference under 35 U.S.C. § 102(b) because it was not published more than one year before applicants' effective filing date. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Applicants maintain that the above remarks and amendments overcome the Examiner's rejection or render the Examiner's rejections moot. Applicants therefore submit that all the pending claims are allowable and respectfully solicit a Notice of Allowance for all of the pending claims. If the Examiner feels that a telephone interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the attorney below.

Version of the Specification with Markings to Show Changes Made by this Amendment

In accordance with 37 C.F.R. §§ 1.121(b)(1)(iii) and 1.121(c)(1)(ii), the following marked up version of the disclosure and/or claims amended herein is provided to show all of the changes relative to the previous version of the portion of the disclosure and/or claims before the amendments herein.

In the Disclosure

Paragraph on page 2, line 29 to page 3, line 5, please amend as follows:

--An apparatus of this kind for the propellant-free administration of a metered amount of a liquid pharmaceutical composition for inhalation is described in detail, for example, in International Patent Application WO 91/14468 entitled "Atomizing Device and Methods" ("the Weston Nebulizer") and also in WO 97/12687 ("the Jaeger Nebulizer A), *cf.* Figures 6a and 6b ("the Jaeger Nebulizer B") and the accompanying description. In a nebulizer of this kind, a pharmaceutical solution is converted by means of a high pressure of up to 500 bar into an aerosol destined for the lungs, which is sprayed. Within the scope of the present specification reference is expressly made to the entire contents of the literature mentioned above.--

Paragraph beginning on page 13, line 29 please amend as follows:

--Further details of the construction are disclosed in PCT applications WO 97/12683~~7~~ and WO 97/20590, to which reference is hereby made and each of which is incorporated herein by reference in their entireties.--

In the Claims:

--38. (Amended) A method for administering a pharmaceutical preparation according to one of claims 1 to 4 or 31 to 37, comprising nebulizing the pharmaceutical preparation in an inhaler selected from the group consisting of: (a) an inhaler according to ~~WO 91/14468~~the Weston Nebulizer, or (b) an inhaler according to ~~Figures 6a and 6b of WO 97/12687~~the Jaeger Nebulizer B.--

--81. (Amended) A method for administering a pharmaceutical preparation according to one of claims 53 to 56, comprising nebulizing the pharmaceutical preparation in an inhaler selected from the group consisting of: (a) an inhaler according to ~~WO 91/14468~~the Weston Nebulizer, or (b) an inhaler according to ~~Figures 6a and 6b of WO 97/12687~~the Jaeger Nebulizer B.--

Certificate of Mailing Under 37 C.F.R. § 1.8(a)
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on April 28, 2003.

Timothy Witkowski

Timothy X. Witkowski
Registration No. 40,232

4-28-2003

Dated

Respectfully submitted,

Timothy Witkowski

Timothy X. Witkowski
Registration No. 40,232
Attorney for Applicants

BOEHRINGER INGELHEIM CORPORATION
Patent Department
900 Ridgebury Road/P.O. Box 368
Ridgefield, CT 06877
Telephone: (203) 798-4310
Facsimile: (203) 798-4408